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09/930,104	08/14/2001	Allan Leslie Friedman	2640/1G826US1	9867

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EXAMINER

WEST, JEFFREY R

ART UNIT PAPER NUMBER

2857

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/930,104	Applicant(s) FRIEDMAN ET AL.	
	Examiner Jeffrey R. West	Art Unit 2857	<i>AW</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 33-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- ~~Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).~~
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 and 3</u> . | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of group I, claims 1-32, in Paper No. 5 is acknowledged. Applicant has not, however, provided corresponding arguments to persuade the Examiner that the restriction requirement should be withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

As shown by the first sentence of 37 CFR 1.143, the traverse to a requirement must be complete as required by 37 CFR 1.111(b) which reads in part: "In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action. . . . The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. . . ." Under this rule, the applicant is required to specifically point out the reasons on which he or she bases his or her conclusions that a requirement to restrict is in error. A mere broad allegation that the requirement is in error does not comply with the requirement of 37 CFR § 1.111. Thus the required provisional election (see MPEP § 818.03(b)) becomes an election without traverse.

***Information Disclosure Statement***

2. Reference "1" on the Information Disclosure Statement filed March 26, 2002, has not been considered because it is a duplicate of reference "5" on the Information Disclosure Statement filed August 14, 2001.

3. References "5" and "7" on the Information Disclosure Statement filed March 26, 2002, have not been considered because they are duplicates of references "4" and "6".

***Drawings***

4. The drawings are objected to because it is unclear why the x-axis of graphs "G", "J", "O", and "P" are labeled both "Impedance" and "Resonance Frequency".

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "15", "17", and "20".

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "18", "19", "71", "72", "74", "76", "80", "82", "84", "96", "110", "112", "114", "142", "144", "146", "750", "770", "860", "880".

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7. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

8. The abstract of the disclosure is objected to because its length exceeds the 150-word limit. Correction is required. See MPEP § 608.01(b).

9. The disclosure is objected to because of the following informalities:

On page 11, lines 27-28, it is unclear what it means to "show values that are exemplify a particular US system."

On page 17, line 2, Applicant refers to "104" as a line while 6b shows "104" as "Phase Detection Logic".

Appropriate correction is required.

### ***Claim Objections***

10. Claims 21 and 24 are objected to because of incorrect dependency.

Claim 21 depends from claim 17, but since claim 17 has no mention of a "prescribed range", it is suggested that claim 21 depend from claim 20, rather than claim 17.

Claim 24 depends from claim 22, but since claim 22 has no mention of a step of "displaying a first message", it is suggested that claim 24 depend from claim 23, rather than claim 22.

Appropriate correction is required.

11. Claims 1, 6, 9, 10, 13, 15, 17, 22, 25, 26, 28, and 31 are objected to because of the following informalities:

In claim 1, "if the impedance data is with acceptable limits" should be ---if the impedance data is within acceptable limits---.

In claim 6, "voltage, a blade resonance frequency" should be ---voltage, or a blade resonance frequency---.

In claim 6, "one of a non-linearity and an evaluation of a continuousness" should be ---one of a non-linearity or an evaluation of a continuousness---.

In claim 9, "wherein the low excitation level" should be ---wherein the lower excitation level--- to be in accordance with the format of claim 7.

In claim 10, "wherein the high excitation level" should be ---wherein the higher excitation level--- to be in accordance with the format of claim 7.

In claim 13, "wherein said excess heated" should be ---wherein said excess heat-  
--.

In claim 15, "at least on of" should be ---at least one of---.

In claim 15, "excess heat indicates that the hand piece/blade is hot; and" should be ---excess heat indicates that the hand piece/blade is hot; or---

In claim 17, "comparing the impedance data of ultrasonic" should be ---  
comparing the impedance data of the ultrasonic---.

In claim 22, "voltage, a blade resonance frequency" should be ---voltage, or a  
blade resonance frequency---.

In claim 22, "one of a non-linearity and an evaluation of a continuousness" should  
be ---one of a non-linearity or an evaluation of a continuousness---.

In claim 25, "wherein the low excitation level" should be ---wherein the lower  
excitation level--- to be in accordance with the format of claim 23.

In claim 26, "wherein the high excitation level" should be ---wherein the higher  
excitation level--- to be in accordance with the format of claim 23.

In claim 28, "on a sheath of he hand piece/blade" should be ---on a sheath of the  
hand piece/blade---.

In claim 31, "excess heat indicates that the hand piece/blade is hot; and" should  
be ---excess heat indicates that the hand piece/blade is hot; or---.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly  
claiming the subject matter which the applicant regards as his invention.

13. Claims 6-32 are rejected under 35 U.S.C. 112, second paragraph, as  
being indefinite for failing to particularly point out and distinctly claim the subject  
matter which applicant regards as the invention.

Claim 6 is rejected as being vague and indefinite because it recites a limitation for "evaluation of a continuousness of the data obtained." This limitation is considered to be vague because it is unclear to what "data obtained" is being referred to since "lowest impedance", "maximum phase" and "blade resonance frequency" data is also obtained. It is assumed that for the prosecution of the application, "data obtained" refers to "impedance data obtained" and therefore, to correct this indefinite limitation, "of the data obtained" should be --of the impedance data obtained--.

Claims 7 and 23 are rejected under 35 U.S.C. 112, second paragraph, because the limitation, "one of a minimum impedance magnitude which is unchanged and a higher minimum impedance than the minimum impedance magnitude obtained at the higher excitation level" is unclear for several reasons.

First, "any impedance data sweep" unclear because there is no previous mention of an "impedance data sweep" or any "impedance data sweeping". Since there is no step for performing a sweep, it is unclear how the conditions of the sweeps can be determined.

Second, the limitation of a "lower excitation level" is considered to be indefinite because it is unclear to one having ordinary skill in the art to the scope of the relative term "lower" (i.e. lower with respect to what?). Also, the claim is providing a "lower excitation level" without any previous excitation level. The limitation of a "higher excitation level" is considered to be indefinite for similar reasons.



Third, the limitation requiring that the "minimum impedance magnitude is unchanged" is considered to be vague and indefinite because it is unclear to one having ordinary skill in the art to what the impedance magnitude is unchanged with respect to or over what type of interval it is unchanged.

Finally, the recited passage of claims 7 and 23 recites the confusing language of "a higher minimum impedance than."

Claims 13, 14, and 30 are rejected under 35 U.S.C. 112, second paragraph because in the limitation, "calculating differences between impedance magnitudes" it is unclear to which magnitudes the limitation is referring. For example, parent claims 7 and 23, include "a minimum impedance magnitude which is less than a minimum impedance magnitude obtained at a higher excitation level" as well as "a minimum impedance magnitude which is unchanged and a higher minimum impedance than the minimum impedance magnitude obtained at the higher excitation level." Because several impedances are defined, it is unclear to one having ordinary skill in the art what impedance magnitudes are having differences calculated.

Claim 17 is rejected as being vague and indefinite because of the limitations providing an "ultrasonic hand piece/blade." This limitation becomes indefinite due to the previous limitations of both "a new blade" and "a known blade." These "new blade" and "known blade" limitations make it unclear to one having ordinary skill in

the art whether "ultrasonic hand piece/blade" refers to one of the "new blade", "known blade" or a different blade altogether.

Claims 8-12, 15, 16, 18-22, 24-29, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, because they incorporate the lack of clarity present in their respective parent claims.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,042,460 to Sakurai et al.

Sakurai discloses an ultrasonic treating apparatus with a device for inhibiting drive when the ultrasonic element is determined to be defective comprising applying a drive signal to an ultrasonic hand piece/blade using an ultrasonic generator (column 3, lines 7-19), obtaining impedance data for the hand piece/blade (column 3, lines 25-28) comparing the impedance data to determine whether the impedance data is within acceptable limits (column 4, lines 35-39) and if the impedance is within

acceptable limits, displaying a message on a display of the generator (column 4, lines 40-42).

Further, since Sakurai discloses applying driving electric power, it is considered inherent that the electric power signal has a current level and a voltage level since it is well-known that power is a function of current and voltage.

Although the invention of Sakurai does not specify that the display be a liquid crystal display, Sakurai does disclose displaying characters and the Examiner takes Official Notice that liquid crystal displays are well known for displaying a plurality of characters to a user (See for example, U.S. Patent No. 5,652,783 to Keba et al., column 7, lines 45-46 or U.S. Patent No. 4,429,369 to Stanly et al., column 1, lines 46-48).

16. Claims 2, 4, 6, 17, 18, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai in view of JP Patent No. 06-003305 to Senda et al.

As noted above, the invention of Sakurai teaches many of the features of the claimed invention and while the invention of Sakurai does teach determining incorrect operation of transducer device, Sakurai discloses determining incorrect operation due to degradation of the device rather than determining a physical defect that causes the incorrect operation.

Senda teaches a method for non-destructively inspecting a piezoelectric element for a micro-crack comprising obtaining impedance data for a known/ideal element (0013, lines 1-4) applying a drive signal for exciting the piezoelectric element over a

predetermined frequency range and obtaining impedance magnitude and impedance phase data of the tested element (0021, lines 1-13), at a plurality current and voltage excitation levels (0010), and comparing the impedance of the element under test to the known element impedance data to determine the correctness of operation (0021, line 13 to 0022, line 7 and 0028). Senda also teaches comparing a magnitude of a lowest impedance (i.e. impedance at resonance) (0019) to the expected waveform to determine non-linearity (0010, 0025, and 0028).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai to teach a method for determining a crack in the device as compared to a known/ideal device, as taught by Senda, because the combination would have provided a method for determining the occurrence of a physical defect thereby allowing the user to correctly diagnose and correct the problem and, as suggested by Senda, provided precise diagnostics quickly, automatically, and without destroying the device under test (0005-0007).

Although the invention of Sakurai and Senda discloses performing the comparison to determine a crack in the transducer rather than the blade itself, since the blade and the transducer are attached a change in impedance due to a crack in the blade would also correspond to the change in impedance observed by the current method (See, for example, page 4, lines 7-16 of the Background of the instant invention that describes the grouped frequency response of the transducer and blade and the correlation between the electric parameters of the transducer and the blade response). Therefore, the combination of Sakurai and Senda operates in

a method that determines the change in impedance indicating a crack in the transducer or the connected blade.

17. Claims 3, 5, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai in view of Senda and further in view of U.S. Patent No. 6,019,775 to Sakurai (Sakurai '775).

As noted above the invention of Sakurai and Senda teaches many of the features of the claimed invention including exciting the hand piece across a predefined frequency range and obtaining impedance data at a plurality of excitation levels, but does specify that the frequency range be from 50 to 60 kHz or that the excitation levels be in the range of 5mA to 50mA.

Sakurai '775 teaches an ultrasonic operation apparatus for performing treatment through utilization of an ultrasonic oscillator comprising a handpiece, serving as a surgical tool, and an apparatus body including a power source unit for supplying electric power to the handpiece (abstract). Sakurai '775 teaches that the handpiece includes a signal generating unit for generating a signal corresponding to a resonant frequency inherent in the ultrasonic element and the probe (abstract). Sakurai '775 also teaches that in ultrasonic surgery tools the oscillator is designed to generate a resonant frequency corresponding to the specific handpiece (column 1, lines 31-47) as well as that the excitation current of the specific handpiece varies based upon the oscillator employed (column 9, lines 41-56).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai and Senda to include sweeping across a predetermined frequency range of 50 to 60 kHz and exciting the handpiece at a current in the range of 5mA to 50mA because Sakurai suggests that each handpiece requires a different frequency sweep range (column 1, lines 31-47) and excitation current (column 9, lines 41-56) based upon the specific makeup of the device being used. Therefore one with ordinary skill in the art would select whatever range is required for the user's specific device, such as 50 to 60 kHz or 5mA to 50mA, as necessary to implement the specific device in its required operation. (See also, for example, U.S. Patent No. 6,391,042 to Cimino, column 1, lines 28-37, U.S. Patent No. 5,406,503 to Williams Jr. et al., column 3, lines 50-60, and U.S. Patent No. 6,387,109 to Davidson et al., column 5, lines 6-26, which teach different ultrasonic devices requiring different frequency ranges and excitation currents for their individual operation.)

### ***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,017,354 to Culp et al. teaches an integrated system for powered surgical tools including a temperature sensor for detecting and indicating the presence of excess heat.

U.S. Patent No. 4,429,369 to Stanly et al. teaches an electro-optical printer that uses a well-known LCD display.

U.S. Patent No. 5,652,783 to Keba et al. teaches a method and apparatus for selectively encoding digital messages in a communication system including a conventional LCD display.

JP Patent No. 07-174802 to Kawaguchi teaches a method for detecting an internal crack in an electronic part.

U.S. Patent No. 6,391,042 to Cimino teaches a pulsed ultrasonic device and method as well as the conventional operating range of 20kHz to 60kHz.

U.S. Patent No. 5,406,503 to Williams Jr. et al. teaches a control system for calibrating and driving ultrasonic transducers including a power amplifier and transformer section that provides a maximum driving voltage of about 380 volts RMS with a maximum current of about 10 mA RMS.

U.S. Patent No. 6,387,109 to Davidson et al. teaches methods and a device for improving blood flow to the heart of a patient including a generator that applies a specific current to acoustically vibrate an assembly in the range of 20kHz to 100 kHz, preferably, 54 kHz to 56 kHz.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. West whose telephone number is (703)308-1309. The examiner can normally be reached on Monday through Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (703)308-1677. The fax phone number

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for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.

jrw  
November 3, 2003

  
MARC S. HOFF  
SUPERVISORY PATENT EXAMINER  
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